# **EXHIBIT E**

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DOS 8/29/1-

Medicare Appeal Number:

1-7208048679



March 15, 2018

J. A. BLOOM 120 NICKLAUS CRICLE SOUTH BURLINGTON, VT 05403

#### Medicare Reconsideration Decision

RE:

Beneficiary: J. Bloom HIC#: \*\*\*\*\*9397A Appellant: J. A. Bloom

Dear J. A. Bloom:

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested an appeal for the services shown under the Appeal Details section.

The appeal decision is UNFAVORABLE. Our decision is that Medicare will make no additional payment. More information on the decision is provided on the next pages. You are not required to take any action.

If you disagree with the decision, you may appeal to an Administrative Law Judge (ALJ). You must file your appeal, in writing, within 60 days of receipt of this letter. For more information on how to appeal, see the page entitled "Important Information About Your Appeal Rights." The amount still in dispute is estimated to be equal to or over \$160.00. However, the ALJ will determine if your appeal case meets the \$160.00 amount in controversy requirement for an ALJ hearing.

#### Contact Information

If you have questions, write or call:

C2C Innovative Solutions, Inc. QIC DME P.O. Box 44163 Jacksonville, FL 32231-4163

*Telephone:* 904-224-7433

Who we are:
We are a Qualified
Independent
Contractor (QIC).
Medicare has
contracted with us to
review your file and
make an independent
decision.

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If this appeal is partially favorable or unfavorable, and it originated from an overpayment, recoupment will begin 31 days from the date of this letter in the absence of an acceptable request for an extended repayment schedule (ERS). Please refer to the original demand letter for information regarding the collection process, interest accrual, and requesting an ERS.

A copy of this letter was also sent to the parties shown below. C2C Innovative Solutions, Inc. was contracted by Medicare to review your appeal. For more information on how to appeal, see the page titled "Important Information About Your Appeal Rights."

Sincerely,

Brian Stotle

CC: Minimed Distribution Corp

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#### Summary of Facts

The service(s) shown below were submitted for payment to Noridian Healthcare Solutions (Noridian). The explanation of the decision was released in a Medicare Summary Notice to the beneficiary and a Remittance Advice to the provider of service. A request for a redetermination appeal was submitted to the Medicare Administrative Contractor (MAC). On January 10, 2018, Noridian Healthcare Solutions (Noridian) completed the appeal and sent notice of the decision to the appropriate parties. On January 24, 2018, a Qualified Independent Contractor (QIC) reconsideration request was received for the services referenced in the "Appeal Details" section. Records contained in the case file included:

- Letter/Statement of Medical Necessity (LMN/SMN)
- Laboratory Result(s)
- Redetermination Letter
- Proof of Delivery (POD)
- Physician Order/Prescription (RX)
- Reconsideration Request
- Durable Medical Equipment Information Form (DIF)
- Medicare Summary Notice (MSN)
- Physician Progress Note(s)
- Certificate of Medical Necessity (CMN)
- Advance Beneficiary Notice (ABN)

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#### Decision

The decision on your appeal is shown below:

Medicare Coverage	Claim Number (ICN)	Procedure /Date of Service
Non- covered	17248721297000	A9276: Disposable Sensor, Cgm Sys - (08/28/17)
Non- covered	17276726489000	A9276: Disposable Sensor, Cgm Sys - (09/28/17)
Non- covered	17306714276000	E0784: Ext Amb Infusn Pump Insulin - (10/09/17)
Non- covered	17311718693000	A9276: Disposable Sensor, Cgm Sys - (11/03/17)

We have determined that J. Bloom and Minimed Distribution Corp is responsible for the denied charges.

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### Explanation of the Decision

Claim Number: 17248721297000

For any item or service to be covered by Medicare, it must fall into a defined Medicare benefit category, it must not be statutorily excluded, it must be reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (SSA), and it must meet other Medicare program requirements for payment. Sections 414.200 through 414.232 of 42 Code of Federal Regulations (CFR) cover payment for durable medical equipment and prosthetic and orthotic devices. The Medicare National Coverage Determinations (NCD) Manual, Publication 100-03, includes NCDs that pertain to certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items. The Medicare Claims Processing Manual, Publication 100-04, Chapter 20, instructs on billing and payment for DMEPOS. The Medicare Program Integrity Manual (PIM), Publication 100-08, Chapter 5, provides guidance on medical review. The manuals are based upon the above cited law and regulations. DME Medicare Administrative Contractors (MACs) publish Local Coverage Determinations (LCDs) and related Policy Articles. The LCDs address the criteria for "reasonable and necessary," based on Social Security Act §1862(a)(1)(A). The articles encompass the non-medical necessity coverage and payment rules.

At issue is payment for A9276-GX (disposable sensors).

The National Coverage Determinations Manual, Chapter 1, Part 4, Section 280.1 states that durable medical equipment (DME) is equipment which can withstand repeated use, is primarily and customarily used to serve a medical purpose, generally is not useful to a person in the absence of an illness or injury, and is appropriate for use in the home. All requirements of the definition must be met before an item can be considered to be DME.

The DME MAC denied payment because the disposable sensors not meet Medicare's meaning of medical equipment.

The Qualified Independent Contractor (QIC) performed an independent review. A letter was submitted by the beneficiary. However, Medicare does not cover the disposable sensor(s). A disposable sensor(s) is considered precautionary equipment. The DME Benefit excludes precautionary items from coverage. Therefore, the item cannot be paid. This does not mean that your doctor did not order the disposable sensors or that it is not helpful to you. It just means that Medicare cannot pay for it. Based on the available documentation, the requirements outlined in the National Coverage Determinations have not been met.

In conclusion, the decision of the QIC is unfavorable.

Claim Number: 17276726489000

Please refer to the Explanation of Decision for Internal Control Number (ICN) 17248721297000 which contains the complete decision for this claim.

Claim Number: 17306714276000

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At issue is payment for the E0784 (external ambulatory infusion pump, insulin).



The Code of Federal Regulations (CFR) Title 42 §424.57 (c) (12) states that the supplier must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery (POD).

The Medicare Program Integrity Manual (PIM), Chapter 4, Section 4.26 states proof of delivery is required in order to verify that the beneficiary received the item(s). An example of proof of delivery to a beneficiary is having a signed delivery slip, and it is recommended that the delivery slip include: 1) The patient's name; 2) The quantity delivered; 3) A detailed description of the item being delivered; 4) The brand name; and 5) The serial number. The long description of the Healthcare Common Procedure Coding System (HCPCS) code, for example, may be used as a means to provide a detailed description of the item being delivered; though suppliers are encouraged to include as much information as necessary to adequately describe the delivered item. The date of signature on the delivery slip must be the date that the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) item was received by the beneficiary or designee. In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply shall be the date of service on the claim.

The DME MAC denied payment because records did not show that you received your insulin pump.

The Qualified Independent Contractor (QIC) performed an independent review. The documentation submitted includes a physician's order for the external ambulatory infusion pump billed. However, Medicare's proof of delivery criteria has not been met because delivery documentation was not submitted to verify the item was delivered. A work order does not support the delivery of the item. A clear record of the delivery must be present to support the items billed were received by the beneficiary. Based on the available documentation, the requirements of the PIM have not been met.

In conclusion, the decision of the QIC is unfavorable.

Claim Number: 17311718693000

Please refer to the Explanation of Decision for Internal Control Number (ICN) 17248721297000 which contains the complete decision for this claim.

#### Who is Responsible for the Bill?

The service (A9276) at issue is denied because it is not a Medicare benefit. Based on this denial, J. Bloom is liable for the claim charge(s).

The provider is responsible for being aware of how to correctly bill Medicare for services (E0784) provided. Providers who bill Medicare must be familiar with coverage provisions that apply to the services that are rendered. Medicare's laws, rules, regulations and policies are readily accessible. When the services are not correctly billed, the provider is held liable for the charges and cannot bill the patient for them. If J. Bloom has paid for the services, J. Bloom should ask the provider for a refund.

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## Other Important Information

If you appeal this decision, the Administrative Law Judge (ALJ) will not consider new evidence unless you show good cause for not presenting the evidence to the QIC. This requirement does not apply to beneficiaries, unless a provider or supplier represents the beneficiary.

For information on how to appeal this decision, refer to the page titled "Important Information About Your Appeal Rights." If you need more information or have any questions, please call 1-800-Medicare (1-800-633-4227) [TTY/TDD: 1-800-486-2048] or the phone number listed on page one.

You can receive copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision. For instructions on how to do this, please see 'Other Important Information' on the page entitled "Important Information About Your Appeal Rights." The request must be submitted in writing to this office.